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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,344	11/08/2005	Pierre Falson	034404-001	5049

21839 7590 09/03/2008

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EXAMINER	
BOESEN, AGNIESZKA	

ART UNIT	PAPER NUMBER
1648	

NOTIFICATION DATE	DELIVERY MODE
09/03/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

Office Action Summary	Application No.	Applicant(s)	
	10/528,344	FALSON ET AL.	
	Examiner	Art Unit	
	AGNIESZKA BOESEN	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 9-26* is/are pending in the application.

4a) Of the above claim(s) *13,14 and 26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7, 9, 12, 15, and 17-22* is/are rejected.

7)☒ Claim(s) *10, 11, 16 and 23-25* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed May 28, 2008 in response to the Office Action of December 7, 2007 is acknowledged and has been entered. Claim 8 has been canceled. Rejections of canceled claim 8 are moot. Claims 1-7 and 9-26 have been amended. Claims 1-7, 9-12, and 15-25 are under examination in this Office Action.

Claim Objections

Objections to claims 5, 6, 10, 11, 16, and 23-25 because of informalities are withdrawn in view of Applicant's amendment.

Specification

The substitute specification filed May 28, 2008 is acknowledged. The substitute specification conforms to 37 CFR 1.125(b) and (c) and has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Rejection of claims 1-3, 12 and 17-22 under 35 U.S.C. 102 (b) as being anticipated by Bolling et al. (US Patent 5,322,769) as evidenced by Weiner et al. (US Patent 6,881,558 B1) **is maintained.**

Applicant's arguments have been fully considered but fail to persuade. Applicant amended claim 1 to recite that the "domain of a toxic membrane protein" is a "transmembrane

domain"; and that the expression system comprises a "nucleotide sequence encoding a soluble protein". Applicants argue that Bolling et al. do not describe an expression system comprising a nucleotide sequence encoding a toxic membrane protein or a transmembrane domain of the membrane protein.

In response to Applicants arguments, with regard to the limitation of a "transmembrane domain" the Office notes that claim1 requires that either the toxic membrane protein or a transmembrane domain of the toxic membrane protein is encoded by the nucleotide sequence. Bolling discloses an expression vector comprising a nucleotide sequence encoding an HIV gp41 toxic membrane protein, as discussed on the record, thus Bolling anticipates the present claims. Bolling does not expressly teach that his expression vector in Example 4 comprises the transmembrane domain of the gp41. However Bolling discloses other expression vectors that do comprise the transmembrane domain of a membrane protein. In Example 10 Bolling expressly discloses an HIV-2 transmembrane protein (TMP) cloned into the CKS soluble fusion protein, wherein the CKS soluble protein is upstream of the nucleotide encoding the dipeptide Asp-Pro. Applicant does not argue the other newly amended limitation: nucleotide sequence encoding a soluble protein, however the Office notes that Bolling discloses an expression system comprising a nucleotide sequence encoding a soluble protein, which is the CKS fusion protein and it is upstream of the nucleotide encoding the dipeptide Asp-Pro (see Examples 4-10).

Thus because Bolling discloses the claimed limitations, Bolling anticipates the present claims and therefore the rejection is maintained.

Rejection of claims 1-3, 12, 17-22 under 35 U.S.C. 102(b) as being anticipated by Chan et al. (EP 0 212 532) as evidenced by Weiner et al. (US Patent 6,881,558 B1) **is maintained.**

Applicant's arguments have been fully considered but fail to persuade. Applicant amended claim 1 to recite that the "domain of a toxic membrane protein" is a "transmembrane domain"; and that the expression system comprises a "nucleotide sequence encoding a soluble protein". Applicants argue that Chan et al. do not include a nucleotide sequence encoding a soluble protein upstream of the nucleotide encoding the dipeptide Asp-Pro.

In response to Applicant's arguments the Office notes that Chan does disclose the soluble protein upstream of the nucleotide encoding the dipeptide Asp-Pro. The TrpLE polypeptide is the soluble protein and it is encoded in the expression vector upstream of the dipeptide Asp-Pro (see claims 1-4, 13, 23 and 29, Figure 1-5, and page 16). Chan disclose the other components of the claimed expression vector as discussed on the record. Thus by this disclosure Chan anticipate the present claims and therefore the rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Rejection of claims 4-7 under 35 U.S.C. 103(a) as being unpatentable over Bolling et al. (US Patent 5,322,769) as applied to claim 1 and further in view of De Beeck et al. (Journal of

Biological Chemistry, 2000, Vol. 275, p. 31428-31437, in IDS of 6/23/2005) and Arechaga et al. (FEBS, 2000, Vol. 482, p. 215-219) as evidenced by Caccaglione et al. (Virus Genes, 2000, Vol. 21, p. 223-226, in IDS of 6/23/2005) **is maintained.**

Rejection of claims 9 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bolling et al. (US Patent 5,322,769) in view of De Beeck et al. (Journal of Biological Chemistry, 2000, Vol. 275, p. 31428-31437, in IDS of 6/23/2005) and Arechaga et al. (FEBS, 2000, Vol. 482, p. 215-219) as evidenced by Caccaglione et al. (Virus Genes, 2000, Vol. 21, p. 223-226, in IDS of 6/23/2005) as applied to claim 1 and further in view of Smith et al. (Gene, 1988, Vol. 67, p. 31-40) and Fiaschi et al. (FEBS, 1995, Vol. 367, p. 145-148) **is maintained.**

Applicant's arguments have been fully considered but fail to persuade. Applicant amended claim 1 to recite that the "domain of a toxic membrane protein" is a "transmembrane domain"; and that the expression system comprises a "nucleotide sequence encoding a soluble protein". Applicants argue that Bolling et al. do not describe an expression system comprising a nucleotide sequence encoding a toxic membrane protein or a transmembrane domain of the membrane protein. Applicant argues that De Beck, Archaga, Ciccaglione, Smith and Fiaschi do not teach expressing toxic membrane proteins or membrane domains thereof.

As discussed above, Bolling does disclose the expression vector comprising a nucleotide sequence encoding a soluble protein upstream of the Asp-Pro dipeptide, and a nucleotide sequence encoding a toxic membrane protein and a transmembrane domain of a toxic membrane protein. De Beck, Archaga, Ciccaglione, Smith and Fiaschi teach the limitations of the dependent claims 4-7, 9 and 15 as discussed on the record. Thus because Bolling teaches the claimed

expression vector and De Beck, Archaga, Ciccaglione, Smith and Fiaschi teach the limitations of the dependent claims 4-7, 9 and 15, the rejections are maintained.

Claim Objection

Claims 10, 11, 16, and 23-25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. It is noted that the elected and examined species of SEQ ID NO: 47 (fusion protein), SEQ ID NO: 41 (pGEXKT expression vector) and SEQ ID NO: 37 (the soluble protein) are free of prior art of record. Additional species will be examined once the generic claim is indicated allowable.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AGNIESZKA BOESEN whose telephone number is (571)272-8035. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Agnieszka Boesen/

Examiner, Art Unit 1648

/Bruce Campell/

Supervisory Patent Examiner, Art Unit 1648